

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0059  
CUSTOMER NUMBER: 723

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Sanofi-Synthelabo, Inc  
Sanofi-Synthelabo Research  
9 Great Valley Parkway  
Malvern, PA 19355

Telephone: (610) -889-6318

RECEIVED  
NOV 21 2006

1 Oct 05 - 277,206

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		97		6	103
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

**ASSURANCE STATEMENTS**

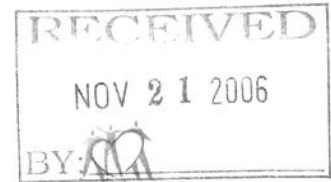
- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

b6, b7c

DATE SIGNED

11/27/06



**sanofi aventis**

Because health matters

**November 16, 2006**

**USDA Annual Report**

**Registration #: 23-R-0059 (1 Oct 2005 – 28 Feb 2006)**

**Explanation of Category 'E' Animals**

**1. Number of Animals and Species Used in:**

Used: 103 Rabbits

Number of Category E animals: 6

**2. Procedure Used:**

6-Rabbits: During a repeat oral toxicity study, two rabbits died within approximately two minutes after dosing. During a different repeat oral toxicity study, four rabbits were discovered dead after having been observed with severe clinical signs.

**3. Justification for procedure:**

The international regulatory process to approve new drug formulations and candidate drugs requires drug safety assessments. The goal of these studies is to investigate the toxicity of a new drug or formulation. The administration of any pain relieving drugs to these animals could interact and alter the results of the study. Animals exhibiting more than momentary pain and distress would be euthanized.

**4. Procedure required by:**

Agency: U.S. Food and Drug Administration,  
Federal Food, Drug, and Cosmetic Act CFR: 505 (4) (i) (1) (A)